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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

January 11, 2007

Ref: **2007-DAL-WL-5**

WARNING LETTER

CERTIFIED MAIL
RETURNED RECEIPT REQUESTED

Mr. Jack F. Cahill, President
Encore Medical, LP
9800 Metric Blvd
Austin, Texas 78758

Dear Mr. Cahill:

During an inspection of your firm, located at the above-referenced address, from September 20 through October 11, 2006, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures orthopedic products for reconstructive surgery of hips, knees, shoulders, and spines and surgical instruments for the implantation of the orthopedic products. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or function of the body.

This inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act, 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (C.F.R.), Part 820.

The inspection revealed violations that include, but are not limited to, the following:

1. Failure to establish and maintain adequate procedures for receiving, reviewing, and evaluating complaints to ensure that they, among other things, are processed in a uniform and timely manner and are evaluated to determine whether the complaint represents an event which is required to be reported to

FDA under 21 C.F.R. part 803, as required by 21 C.F.R. § 820.198(a) and (d). For example, of the 108 complaints your firm received from January 2, 2006, through March 2, 2006, 21 complaints had incomplete information or investigations and 19 complaints were not fully investigated or documented for possible medical device reporting to FDA. Additionally, your firm's sales representatives have not always timely relayed complaints to your firm for an adequate review and investigation.

2. Failure to adequately review, evaluate, and investigate complaints involving the possible failure of a device, labeling, or packaging to meet any of its specifications, as required by 21 C.F.R. § 820.198(c). For example:

   a. Your firm failed to adequately determine, evaluate, and document the root cause of how and why the bipolar head of the Bipolar Hemi Hip was dislocated from the patient's acetabulum in Complaint 7027, dated 2/8/06. Your firm documented that it could not determine the root cause of the device failure. A review of your firm's complaint file revealed that your firm received 13 similar complaints from a foreign distributor and that your sales representatives complained that this type of problem was being reported rather frequently.

   b. Your firm failed to adequately determine, evaluate, and document the root cause of how and why the attachment screw in the tibial insert of the 3D Knee System in a patient was backing out in Complaint 7185, dated 3/16/06. Your firm documented that its review of the manufacturing records revealed no attributes that could have contributed to this event. A review of your firm's complaint file revealed that your firm received 12 complaints of attachment screws backing out from 8/2004 through 6/2005 and initiated two engineering changes (ECO 4590 and 6484) in 11/2004 and 7/2006.

3. Failure to adequately establish and maintain procedures for implementing corrective and preventive action, as required by 21 C.F.R. § 820.100(a). For example, in January 2006, your firm received multiple user complaints of [redacted] coming out of the liner impactor (a surgical instrument) used to implant the femoral head. Your firm's complaint file documented that the [redacted] will fail after repeat impactions and that your product development team will review the design and possibly remove the [redacted] Approximately nine months after you received the complaints about the [redacted] your firm still has not conducted and documented a design assessment, a root cause analysis, or implemented a corrective action plan to address this quality issue. See Complaint 6856, 6857, 6858, and CAPA Report 7857, dated 7/11/06.

4. Failure to establish and maintain procedures for changes to specifications, method, process, or procedures, including verification or validation of such changes according to 21 C.F.R. § 820.75, as required by 21 C.F.R. § 820.70(b), and failure to establish and maintain procedures for rework, including retesting and evaluation of the nonconforming product after rework, to ensure that the product meets its current approved specifications, as required by 21 C.F.R. § 820.90(b)(2). For example, your contract manufacturer delivered Speedblocks (a surgical instrument) that did not meet your firm's approved specifications, and your firm decided to rework them in-house. Complaint 7208, dated 3/23/06, documented that your firm's rework caused the premature failure of the Speedblocks during use in surgery, that the Speedblocks split in half, and that your firm conducted a recall of this product. Your firm did not evaluate and document any adverse effect of its rework upon the product. Your firm's rework changed the device specifications without validating the changes to determine their impact on the device functionality, users, and patients. Additionally, your firm has not documented the changes of device specifications in its engineering change order.

Our inspection also revealed that your devices are misbranded under Section 502(t)(2) of the Act, 21 U.S.C. § 352(t)(2), in that your firm failed or refused to furnish material or information respecting the device that is required by or under Section 519 of the Act, 21 U.S.C. § 360i, and 21 C.F.R. Part 803 – Medical Device Reporting (MDR) regulation. Significant deviations include, but are not limited to, the following:

1. Failure to report to FDA within 30 calendar days after the day of becoming aware that a device you market may have caused or contributed to death or serious injury, or a device you market has malfunctioned and this device or a similar device that you market would be likely to cause death or serious injury if the malfunction were to recur, as required by 21 C.F.R. § 803.50(a). For example, Complaint 6977 received on 2/6/06 documented that the physician explanted a malfunctioned part because the socket was dissociated from the stem of the socket insert of the Reverse Shoulder System (Part 508-00-008). However, as of FDA's most recent inspection, this complaint had not been reported to FDA.

2. Failure to develop, maintain, and implement adequate written MDR procedures that include internal systems for timely and effective identification, communication, and evaluation of events that may be subject to MDR requirements and that include documentation and record keeping requirements for information that was evaluated to determine if an event is

reportable to FDA, as required by 21 C.F.R. § 803.17. Events that may be subject to MDR requirements were not fully evaluated or documented. For example:

a. Complaint 6859 received on 1/10/06 documented that a surgical instrument (Part 803-03-052) broke while trailing during surgery and that the surgery was delayed for 15 minutes. Your firm documented that the root cause of the problem was due to a "weak design." However, your firm did not obtain and document information received from the user to determine whether any adverse event happened to the involved patient or whether an explant was performed to remove the broken part.

b. Complaint 7208 received on 3/23/06 documented that an implant part (Speedblock, Part 800-01-369) was split in half during surgery. Your firm did not document whether the surgery was delayed, any adverse event happened to the involved patient, or an explant was performed to remove the broken part.

On November 19, 2006, we received a response from you dated November 8, 2006, concerning our investigator's observations noted on the Form FDA 483, List of Inspectional Observations, which was issued to you. Your response is not complete in that your firm has not implemented a comprehensive corrective action plan to correct systemic issues, as well as the specific issues cited in this warning letter. Also, please be aware that finished devices intended for human use, regardless of their classification, are generally subject to the CGMP requirements of the QS regulation. See 21 C.F.R. § 820.1.

You should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties. Also, federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, premarket approval applications for Class III devices to which the QS regulation deviations are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations,

or similar violations, from occurring again. Include documentation of the corrective action you have taken. If your planned corrections will occur over time, please include a timetable for implementation of these corrections. If the corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Thao Ta, Compliance Officer, Dallas District Office, Food and Drug Administration, HFR-SW140, 4040 N. Central Expressway, Suite 300, Dallas, TX 75240. If you have any questions about the contents of this letter, please contact Mr. Ta at 214-253-5217.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Form FDA-483 issued at the closeout of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality assurance systems. You should investigate and determine the causes of the violations, and take prompt actions to correct the violations and to bring your products into compliance.

Sincerely,

Michael A. Chappell
Dallas District Director

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